

Amendments to the Claims

1. (currently amended) A method of treating a disease or medical condition in a patient comprising administering a therapeutic amount of a drug ester condensation aerosol to the patient by inhalation,

wherein the condensation aerosol is formed by heating a thin layer containing the drug ester, on a solid support, to produce a vapor of the drug ester, and condensing the vapor to form a condensation aerosol characterized by less than 10% drug ester degradation products by weight, and having an MMAD of less than 5 microns. ~~3- μ m and less than 5% drug ester degradation products, to a patient by inhalation, upon activation by the patient of the formation of, and delivery of, the condensation aerosol.~~

2. (currently amended) The method of ~~of~~ according to claim 1, wherein ~~said the~~ condensation aerosol is characterized by an MMAD of less than 3 microns. ~~formed by~~

a. ~~volatilizing a drug ester under conditions effective to produce a heated vapor of the drug ester; and~~

b. ~~condensing the heated vapor of drug ester to form condensation aerosol particles.~~

3. (currently amended) The method according to claim 2 1, wherein ~~said administration~~ results in a peak plasma drug ester concentration ~~of said drug ester~~ is reached in less than 0.1 hours.

4. (cancelled)

5. (currently amended) The method according to claim 3 1, wherein the ~~administered~~ condensation aerosol is formed at a rate greater than 0.5 mg/second.

6. (original) The method according to claim 1, wherein at least 50% by weight of the condensation aerosol is amorphous in form.

7.-10. (cancelled)

11. (currently amended) The method according to ~~claim 7~~ claim 1, wherein ~~said ester of an antibiotic; ester of an anticonvulsant; ester of an antidepressant; ester of an antihistamine; ester of an antiparkinsonian drug; ester of a drug for migraine headaches; ester of a drug for the treatment of alcoholism; ester of a muscle relaxant; ester of an anxiolytic; ester of a nonsteroidal anti-inflammatory;~~

~~ester of an other analgesic; or ester of a steroid condensation aerosol has an inhalable aerosol mass density of between 0.1 mg/L and 100 mg/L when delivered~~ the therapeutic amount of drug ester condensation aerosol comprises between 0.1 mg and 100 mg of the drug ester delivered in a single inspiration.

12.-15. (cancelled)

16. (currently amended) A method of administering a drug ester condensation aerosol to a patient ~~to achieve a peak plasma drug concentration rapidly, comprising administering the drug ester condensation aerosol to the patient by inhalation, an aerosol of a drug ester having less than 5%~~ wherein the drug ester condensation aerosol is formed by heating a thin layer containing the drug ester, on a solid support, to produce a vapor of the drug ester, and condensing the vapor to form a condensation aerosol characterized by less than 10% drug ester degradation products by weight, and an MMAD of less than 5 microns. ~~3 microns wherein the peak plasma concentration of the drug ester is achieved in less than 0.1 hours.~~

17. (cancelled)

18. (currently amended) A kit for delivering a drug ester condensation aerosol comprising:
a) ~~a.~~ a thin ~~coating of a drug ester composition and~~ layer containing the drug ester, on a solid support, and
b) ~~b.~~ a device for providing the condensation aerosol, wherein the condensation aerosol is formed by heating the thin layer to produce a vapor of the drug ester, and condensing the vapor to form a condensation aerosol characterized by less than 10% drug ester degradation products by weight, and an MMAD of less than 5 microns. ~~dispensing said thin coating as a condensation aerosol.~~

19. (cancelled)

20. (currently amended) The kit ~~of~~ according to claim 18, wherein the device ~~for dispensing said coating of a drug ester composition as an aerosol~~ comprises:
(a) ~~a.~~ a flow through enclosure containing the solid support,
(b) ~~—contained within the enclosure, a metal substrate with a foil-like surface and having a thin coating of a drug ester composition formed on the substrate surface,~~

(e) ~~b.~~ a power source that can be activated to heat the ~~substrate to a temperature effective to volatilize the drug ester composition contained in said coating~~ solid support, and

(d) ~~c.~~ ~~inlet and exit portals~~ at least one portal through which air can be drawn ~~through said device by inhalation,~~

wherein ~~heating the substrate by activation of the power source is effective to produce a vapor of the drug ester, and drawing air through the enclosure is effective to condense the vapor to form the condensation aerosol.~~ form a drug ester vapor containing less than 5% drug ester degradation products, and drawing air through said chamber is effective to condense the drug ester vapor to form aerosol particles wherein the aerosol has an MMAD of less than 3 microns.

21. (currently amended) The kit according to claim 20, wherein the heat for heating the ~~substrate~~ solid support is generated by an exothermic chemical reaction.

22. (currently amended) The kit according to claim 21, wherein said ~~the~~ exothermic chemical reaction is oxidation of combustible materials.

23. (currently amended) The kit according to claim 20, wherein the heat for heating the ~~substrate~~ solid support is generated by passage of current through an electrical resistance element.

24. (currently amended) The kit according to Claim 20, wherein ~~said substrate~~ the solid support has a surface area dimensioned to accommodate a therapeutic dose of the drug ester. ~~ester composition in said coating.~~

25. (currently amended) The kit according to claim 18, ~~wherein a peak~~ wherein peak plasma drug ester concentration ~~of drug ester is obtained is reached~~ in less than 0.1 hours ~~after delivery of the condensation aerosol to the pulmonary system.~~

26. (currently amended) The kit ~~of~~ according to claim 18, further including instructions for use.

27. (new) The method according to claim 1, wherein the condensation aerosol is characterized by an MMAD of 0.2 to 5 microns.

28. (new) The method according to claim 2, wherein the condensation aerosol is characterized by an MMAD of 0.2 to 3 microns.

29. (new) A method of treating a disease or medical condition in a patient comprising administering a therapeutic amount of a drug ester condensation aerosol to the patient by inhalation, wherein the condensation aerosol is formed by heating a thin layer containing the drug ester, on a solid support, to produce a vapor of the drug ester, and condensing the vapor to form a condensation aerosol characterized by less than 10% drug ester degradation products by weight, and an MMAD of less than 5 microns, and

wherein the drug ester is selected from the group consisting of an ester of 2-pentenylpenicillin, an ester of 4-amino-3-hydroxybutyric acid, an ester of acamprosate, an ester of aceclofenac, an ester of alclofenac, an ester of alminoprofen, an ester of amfenac, an ester of amoxicillin, an ester of ampicillin, an ester of amylpenicillin, an ester of apomorphine, an ester of aspirin, an ester of azidocillin, an ester of baclofen, an ester of benoxaprofen, an ester of benzylpenicillin, an ester of bermoprofen, an ester of betamethasone, an ester of bromfenac, an ester of bucloxate, an ester of bufexamac, an ester of bumadizon, an ester of butibufen, an ester of calcium N-carboamoylaspartate, an ester of carbenicillin, an ester of carbidopa, an ester of carfecillin, an ester of carindacillin, an ester of carprofen, an ester of cefazolin, an ester of cefmetazole, an ester of cefoxitin, an ester of cephacetrile, an ester of cephalixin, an ester of cephaloglycin, an ester of cephaloridine, an ester of a cephalosporin, an ester of cephalotin, an ester of a cephamycin, an ester of cepharin, an ester of cephradine, an ester of chloral betaine, an ester of chlorazepate, an ester of chlorobutin penicillin, an ester of chloroprednisone, an ester of cinchophen, an ester of cinmetacin, an ester of clidanac, an ester of clocortolone, an ester of clometacin, an ester of clometocillin, an ester of clonixin, an ester of clopriac, an ester of cloxacillin, an ester of cortisone, an ester of cyclacillin, an ester of desonide, an ester of desoximetasone, an ester of dexamethasone, an ester of diclofenac, an ester of dicloxacillin, an ester of diflunisal, an ester of difluprednate, an ester of diphenicillin, an ester of estradiol, an ester of ethanedisulfonate, an ester of etodolac, an ester of fenclozate, an ester of fenoprofen, an ester of fexofenadine, an ester of fludrocortisone, an ester of flumethasone, an ester of flunisolide, an ester of fluocortolone, an ester of fluprednisolone, an ester of flurbiprofen, an ester of flutiazin, an ester of gabapentin, an ester of heptylpenicillin, an ester of hetacillin, an ester of hydrocortisone, an ester of ibufenac, an ester of ibuprofen, an ester of indomethacin, an ester of indoprofen, an ester of ketoprofen, an ester of ketorolac, an ester of levodopa, an ester of loxoprofen, an ester of meclofenamate, an ester of meprednisone, an ester of methicillin, an ester of metampicillin, an ester of methylprednisolone, an ester of nafcillin, an ester of naproxen, an ester of oxaprozin, an ester of paramethasone, an ester of a penicillin, an ester of pirprofen, an ester of prednisolone, an ester of

prednisone, an ester of pregnan-3-alpha-ol-20-one, an ester of prodolic acid, an ester of S-adenosylmethionine, an ester of salsalate, an ester of sulindac, an ester of testosterone, an ester of thioclate, an ester of tianeptine, an ester of tofenamate, an ester of tolfenamic acid, an ester of tolmetin, an ester of triamcinolone, an ester of valproate and an ester of vigabatrin.

30. (new) The method according to claim 29, wherein the condensation aerosol is characterized by an MMAD of less than 3 microns.

31. (new) The method according to claim 29 wherein the condensation aerosol is characterized by an MMAD of 0.2 to 5 microns.

32. (new) The method according to claim 30, wherein the condensation aerosol is characterized by an MMAD of 0.2 to 3 microns.

33. (new) The method according to claim 29, wherein peak plasma drug ester concentration is reached in less than 0.1 hours.

34. (new) The method according to claim 29, wherein the condensation aerosol is formed at a rate greater than 0.5 mg/second.

35. (new) The method according to claim 29, wherein at least 50% by weight of the condensation aerosol is amorphous in form.

36. (new) The method according to claim 29, wherein the therapeutic amount of drug ester condensation aerosol comprises between 0.1 mg and 100 mg of drug ester delivered in a single inspiration.

37. (currently amended) A method of administering a drug ester condensation aerosol to a patient comprising administering the drug ester condensation to the patient by inhalation, wherein the drug ester condensation aerosol is formed by heating a thin layer containing the drug ester, on a solid support, to produce a vapor of the drug ester, and condensing the vapor to form a condensation aerosol characterized by less than 10% drug ester degradation products by weight, and an MMAD of less than 5 microns, and

wherein the drug ester is selected from the group consisting of an ester of 2-pentenylpenicillin, an ester of 4-amino-3-hydroxybutyric acid, an ester of acamprosate, an ester of aceclofenac, an ester of alclofenac, an ester of alminoprofen, an ester of amfenac, an ester of amoxicillin, an ester of ampicillin, an ester of amylpenicillin, an ester of apomorphine, an ester of aspirin, an ester of azidocillin, an ester of baclofen, an ester of benoxaprofen, an ester of benzylpenicillin, an ester of bermoprofen, an ester of betamethasone, an ester of bromfenac, an ester of bucloxate, an ester of bufexamac, an ester of bumadizon, an ester of butibufen, an ester of calcium N-carboamoylaspartate, an ester of carbenicillin, an ester of carbidopa, an ester of carfecillin, an ester of carindacillin, an ester of carprofen, an ester of cefazolin, an ester of cefmetazole, an ester of cefoxitin, an ester of cephradine, an ester of cephalixin, an ester of cephaloglycin, an ester of cephaloridine, an ester of a cephalosporin, an ester of cephalotin, an ester of a cephamycin, an ester of cepharin, an ester of cephradine, an ester of chloral betaine, an ester of chlorazepate, an ester of chlorobutin penicillin, an ester of chloroprednisone, an ester of cinchophen, an ester of cinmetacin, an ester of clidanac, an ester of clocortolone, an ester of clometacin, an ester of clometocillin, an ester of clonixin, an ester of clopricac, an ester of cloxacillin, an ester of cortisone, an ester of cyclacillin, an ester of desonide, an ester of desoximetasone, an ester of dexamethasone, an ester of diclofenac, an ester of dicloxacillin, an ester of diflunisal, an ester of difluprednate, an ester of diphenicillin, an ester of estradiol, an ester of ethanedisulfonate, an ester of etodolac, an ester of fenclozate, an ester of fenoprofen, an ester of fexofenadine, an ester of fludrocortisone, an ester of flumethasone, an ester of flunisolide, an ester of fluocortolone, an ester of fluprednisolone, an ester of flurbiprofen, an ester of flutiazin, an ester of gabapentin, an ester of heptylpenicillin, an ester of hetacillin, an ester of hydrocortisone, an ester of ibufenac, an ester of ibuprofen, an ester of indomethacin, an ester of indoprofen, an ester of ketoprofen, an ester of ketorolac, an ester of levodopa, an ester of loxoprofen, an ester of meclofenamate, an ester of meprednisone, an ester of methicillin, an ester of metampicillin, an ester of methylprednisolone, an ester of nafcillin, an ester of naproxen, an ester of oxaprozin, an ester of paramethasone, an ester of a penicillin, an ester of pirprofen, an ester of prednisolone, an ester of prednisone, an ester of pregnan-3-alpha-ol-20-one, an ester of prodolic acid, an ester of S-adenosylmethionine, an ester of salsalate, an ester of sulindac, an ester of testosterone, an ester of thioctate, an ester of tianeptine, an ester of tofenamate, an ester of tolfenamic acid, an ester of tolmetin, an ester of triamcinolone, an ester of valproate and an ester of vigabatrin.

38. (new) The kit according to claim 18, wherein the condensation aerosol is characterized by an MMAD of less than 3 microns.

39. (new) The kit according to claim 18 wherein the condensation aerosol is characterized by an MMAD of 0.2 to 5 microns.

40. (new) The kit according to claim 38, wherein the condensation aerosol is characterized by an MMAD of 0.2 to 3 microns.

41. (new) The kit according to claim 20, wherein the solid support has a surface to mass ratio of greater than 1 cm² per gram.

42. (new) The kit according to claim 20, wherein the solid support has a surface to volume ratio of greater than 100 per meter.

43. (new) The kit according to claim 20, wherein the solid support is a metal foil.

44. (new) The kit according to claim 43, wherein the metal foil has a thickness of less than 0.25 mm.

45. (new) A kit for delivering a drug ester condensation aerosol comprising:

a. a thin layer containing the drug ester, on a solid support, and

b. a device for providing the condensation aerosol, wherein the condensation aerosol is formed by heating the thin layer to produce a vapor of the drug ester, and condensing the vapor to form a condensation aerosol characterized by less than 10% drug ester degradation products by weight, and an MMAD of less than 5 microns,

wherein the drug ester is selected from the group consisting of an ester of 2-pentenylpenicillin, an ester of 4-amino-3-hydroxybutyric acid, an ester of acamprosate, an ester of aceclofenac, an ester of alclofenac, an ester of alminoprofen, an ester of amfenac, an ester of amoxicillin, an ester of ampicillin, an ester of amylpenicillin, an ester of apomorphine, an ester of aspirin, an ester of azidocillin, an ester of baclofen, an ester of benoxaprofen, an ester of benzylpenicillin, an ester of bermoprofen, an ester of betamethasone, an ester of bromfenac, an ester of bucloxate, an ester of bufexamac, an ester of bumadizon, an ester of butibufen, an ester of calcium N-carboamoylaspartate, an ester of carbenicillin, an ester of carbidopa, an ester of carfecillin, an ester of carindacillin, an ester of carprofen, an ester of cefazolin, an ester of cefmetazole, an ester of cefoxitin, an ester of cephacetrile, an ester of cephalixin, an ester of cephaloglycin, an ester of cephaloridine, an ester of a cephalosporin, an ester of cephalotin, an ester of a cephamycin, an ester of cepharin, an ester of cephradine, an ester of chloral betaine, an ester of

chlorazepate, an ester of chlorobutin penicillin, an ester of chloroprednisone, an ester of cinchophen, an ester of cinmetacin, an ester of clidanac, an ester of clocortolone, an ester of clometacin, an ester of clometocillin, an ester of clonixin, an ester of clopiac, an ester of cloxacillin, an ester of cortisone, an ester of cyclacillin, an ester of desonide, an ester of desoximetasone, an ester of dexamethasone, an ester of diclofenac, an ester of dicloxacillin, an ester of diflunisal, an ester of difluprednate, an ester of diphenicillin, an ester of estradiol, an ester of ethanedisulfonate, an ester of etodolac, an ester of fenclozate, an ester of fenoprofen, an ester of fexofenadine, an ester of fludrocortisone, an ester of flumethasone, an ester of flunisolide, an ester of fluocortolone, an ester of fluprednisolone, an ester of flurbiprofen, an ester of flutiazin, an ester of gabapentin, an ester of heptylpenicillin, an ester of hetacillin, an ester of hydrocortisone, an ester of ibufenac, an ester of ibuprofen, an ester of indomethacin, an ester of indoprofen, an ester of ketoprofen, an ester of ketorolac, an ester of levodopa, an ester of loxoprofen, an ester of meclofenamate, an ester of meprednisone, an ester of methicillin, an ester of metampicillin, an ester of methylprednisolone, an ester of nafcillin, an ester of naproxen, an ester of oxaprozin, an ester of paramethasone, an ester of a penicillin, an ester of pirprofen, an ester of prednisolone, an ester of prednisone, an ester of pregnan-3-alpha-ol-20-one, an ester of prodolic acid, an ester of S-adenosylmethionine, an ester of salsalate, an ester of sulindac, an ester of testosterone, an ester of thioclate, an ester of tianeptine, an ester of tofenamate, an ester of tolfenamic acid, an ester of tolmetin, an ester of triamcinolone, an ester of valproate and an ester of vigabatrin.

46. (new) The kit according to claim 45, wherein the device comprises:

- a. a flow through enclosure containing the solid support,
- b. a power source that can be activated to heat the solid support, and
- c. at least one portal through which air can be drawn by inhalation,

wherein activation of the power source is effective to produce a vapor of the drug ester, and drawing air through the enclosure is effective to condense the vapor to form the condensation aerosol.

47. (new) The kit according to claim 45, wherein the condensation aerosol is characterized by an MMAD of less than 3 microns.

48. (new) The kit according to claim 45 wherein the condensation aerosol is characterized by an MMAD of 0.2 to 5 microns.

49. (new) The kit according to claim 47, wherein the condensation aerosol is characterized by an MMAD of 0.2 to 3 microns.